Reference Pricing Subcommittee Report
West Virginia Pharmaceutical Cost Management Council (Rx Council)

1. **Executive Summary**:

West Virginia pays higher prices for its most-prescribed drugs than do consumers in other advanced countries such as Australia or Canada. West Virginia's drug burden is 59% above the national average, the second highest in the US.[1] If West Virginia obtained Australian prices for the top 10 drugs purchased in PEIA, the annual savings would exceed $13 million per year.[2] Using the Federal Supply Schedule would save less, about $10 million per year.[3] Extending Australian prices to the top 10 drugs in Medicaid results in at least an additional $10 million saved per year.[4] If additional drugs beyond the top 10 are included, the savings multiply significantly. If all West Virginians paid FSS or Australian prices for drugs, the annual savings would exceed $500 million per year.[5]

Drug companies are unlikely to voluntarily extend these prices to West Virginia. Three legislative steps are proposed to reduce drug prices:

a. Permit West Virginia to act as a virtual wholesaler of drugs. The drugs would be purchased from three sources: domestically through a competitive bid tender process; internationally from the countries designated by federal law as permissible for drug importation (including Canada and Australia); and domestically through a State license process. Contract the wholesaler function to a reputable drug wholesaler who will be required to pass the savings on to pharmacies in this State. Permit PEIA reimbursement of approved internet purchases as an interim step.

b. Permit an appropriate State agency to issue a State license for certain patented drugs if the drug company harms public health by refusing to negotiate a reasonable price. Prices in excess of the Australian PBS prices will be presumed unreasonable. Drug companies would be permitted to rebut the presumption by demonstrating the therapeutic cost-benefit of the particular drug (ie 'economic evaluation'). The decision of the Rx Council could be appealed to the WV Supreme Court. Under federal law, the State may take advantage of this program; it may be possible to extend this program to all West Virginians by asserting the police power of the State to protect the health and safety of its citizens.

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[1] Sager (2004). West Virginia utilization is 42% above the national average; prices and per capita income are 13% and 23% below the national average, respectively.
[2] See the spreadsheet at Appendix A.
[3] See the spreadsheet at Appendix A.
[4] See the spreadsheet at Appendix B.
[5] Sager (2004) (FSS comparison only).

c. Regulate pharmaceutical marketing within the State.

This report also discusses internal reference pricing in PEIA, without a recommendation at this time.

2. **Detailed Proposals**:

a. Virtual Wholesaler.

i. The State should act as a virtual wholesaler to obtain lower drug prices.

1. Involvement of local pharmacies in counseling patients is important to good medical care. All drugs will be sold through local pharmacies.

2. The State will contract with a reputable drug wholesale firm which will be required to pass the low prices on to pharmacies in this State.

3. The pharmacies will also pass the savings on, with a reasonable mark up and dispensing fee.

ii. The virtual wholesaler will tap into three sources of low-cost drugs: domestic bidding, international importation, and State licenses.

1. Domestic bidding

a. West Virginia will issue RFPs for sealed bids for specific quantities of specific pharmaceuticals.

b. Demand will be steered to the successful products through lower (or zero) co-pays and deductibles, and other inducements.

c. West Virginia may join with other States in this procurement process.

2. International sources.

a. If federal law changes under currently proposed Bills in Congress, or if the Secretary of HHS certifies the safety and efficacy of drug imports, West Virginia's ability to utilize this supply channel may well depend upon advance planning.

b. Several States (such as Illinois & Minnesota) are developing detailed plans to import prescription drugs from Canada. Canadian supplies will not be sufficient to fill the expected demand.

c. West Virginia should cooperate with other States in developing these plans, but should also independently explore importation from other sources, such as Australia, England, Italy, Spain, New Zealand, France, Germany, Sweden, Denmark, Norway, the Netherlands, Belgium and Switzerland.

3. State licenses are described in Section b below.

iii. As an intermediate step pending federal approval of drug importation, PEIA will immediately begin to reimburse patients for certain drugs the patients order themselves from State-approved internet pharmacies. PEIA will issue a list of approved drugs and approved internet pharmacies, and may waive co-pays and deductibles to encourage the practice. It is understood that the FDA has agreed not to block this process in the interim. Reimbursement should cease when the wholesale system is fully implemented.

b. Issuing State Licenses For Patented Drugs

i. The federal government currently enjoys the power to compel a pharmaceutical company to issue a license for a patented drug.

ii. West Virginia can enact a similar statute to provide for its own employees and programs such as PEIA and Medicaid.

iii. The process of issuing a State license:

1. The process will be initiated if the pharmaceutical harms the public health or the fiscal health of the State by refusing to negotiate or bid a reasonable price. Any price in excess of the Australian PBS price will be presumed unreasonable.

2. Drug companies will be permitted to give evidence of the therapeutic and cost-benefit of the particular drug (ie 'economic evaluation') in the process of determining a reasonable license fee. If the companies choose to offer economic evaluation evidence, it must provide copies of the relevant evidence previously submitted to the

Australian PBS or the English National Institute for Clinical Effectiveness for that drug and all similar drugs.

3. This process is not price fixing or rate setting, but is a commitment by the State to pay more for valuable, innovative drugs. Accordingly, R&D costs and marketing expenses are not relevant here. The relevant evidence is whether the drug in question provides additional therapeutic benefits at a reasonable cost.

4. The State agency will hold a public administrative hearing, after due notice, of its intent to issue a State license for a particular drug. Any interested party (including drug companies, other State agencies, and members of the public) will be permitted to appear and present oral and written evidence. Testimony will be under oath, under penalties of perjury. The agency will have relevant subpoena powers over any party choosing to give evidence at the hearing. Parties and the State agency shall have the ability to cross-examine witnesses.

5. The decision of the State agency may be appealed to the WV Supreme Court under normal administrative law standards of review.

6. In order to facilitate the widest possible market for the licensed drug, the State will recognize, on comity and full faith and credit grounds, the decision of any other State to issue a similar license under the laws of that State.

iv. After a decision by the State agency to issue a license, the State will select one or more pharmaceutical companies to produce generic versions of the drug. The State may enter into a binding long-term purchase commitment with this generic company, and may join with other States in making a joint purchase commitment. The generic company will be responsible for FDA approval.

v. All drugs produced under this provision will be sold through the virtual wholesale system described above, to pharmacies located in this State.

vi. While this program will be available primarily to the State and its employees (PEIA, Medicaid), it may be possible to extend the program to all citizens of West Virginia under the police power of the State to protect the health of its citizens. This extension would likely be challenged constitutionally.

c. Regulating Pharmaceutical Marketing

i. In several recent settlements, pharmaceutical companies and pharmaceutical benefit managers have paid multi-million dollar penalties for abusive and illegal marketing practices.

ii. In order to determine whether such practices are occurring in West Virginia, the following legislative enactments are suggested:

1. Regulate the practice of pharmaceutical marketing in the State, requiring registration and payment of a modest annual license fee ($250) for each drug representative who markets within the State. Pharmacy benefit managers (PBMs) will also be required to register and be subject to regulation. Carve out PEIA and other State business from Medicaid and private payors to respond to potential pre-emption challenges.

2. Extend fraud & abuse, State 'Stark II', and qui tam whistleblower laws to the marketing activities of pharmaceutical companies, PBMs and their agents and employees in West Virginia.

3. Require public disclosure of potentially abusive marketing arrangements and practices. Require public disclosure of direct or indirect financing or support of any patient advocacy group operating in this State by pharmaceutical companies or their agents.

4. Grant an appropriate State agency rulemaking authority to further implement these provisions.

iii. Several States (such as Maine & the District of Columbia) have recently adopted such laws, which can be utilized as models.

d. Internal Reference Pricing in PEIA.

i. The following is not a recommendation of the subcommittee, but is a discussion of one of the options for reducing State expenditures on drugs.

ii. PEIA currently utilizes tiered co-pays for certain prescription drugs. In a tiered co-pay, generics might have a $5 co-pay,

preferred brand name drug might have a $15 co-pay, and non-preferred drugs have a $30 co-pay.

iii. Internal reference pricing (IRP) would accentuate the cost-shifting to consumers who choose the higher priced drugs when lower priced drugs are available.

iv. Under IRP, the payor identifies the most cost-effective drug in a class and fully reimburses for that drug (ie, zero co-pay and deductible). All other drugs in that class are reimbursed at the same dollar amount. The drug companies are completely free to set their own prices, but if they choose to set a price above the IRP reimbursement amount, the consumer must pay the difference.

v. IRP is used extensively in Australia and in several European countries. It is not a price control, but is a cap on government reimbursement.

3. Sources Used For This Report

Professor Outterson wrote the first draft of this report, relying upon the presentations made to the Rx Council and the work of subcommittee members Shana Phares (Deputy Director, WVDHHR) and Peggy King (Medicaid) and Rx Council Member Felice Joseph (PEIA). The subcommittee also employed research assistants Jonathan Bomparti, David Davis and Heather Cameron (law students at WVU) and Sanjoy Roy (WVU College of Pharmacy graduate student). WVU Professor of Pharmacy Suresh Madhavan also provided early comments. Boston University Professor Alan Sanger provided helpful comments.